

APPENDIX II: Clean Copy of Claims upon Entry of Amendments

13) 1. (Twice amended) A drug delivery composition for delivering a drug to the colonic region comprising a starch capsule containing the drug and wherein the starch capsule is provided with a coating such that the drug is predominantly released from the capsule in the colon and/or terminal ileum.

2. A drug delivery composition according to claim 1 wherein the coating comprises a material which dissolves at a pH of 5 or above.

3. A drug delivery composition according to claim 1 wherein the coating comprises a material which is redox-sensitive.

4. A drug delivery composition according to claim 3 wherein the coating comprises an azopolymer or a disulphide polymer.

5. A drug delivery composition according to claim 1 wherein the coating comprises a material which is degraded by enzymes or bacteria present in the colon.

6. A drug delivery composition according to claim 2 wherein the coating comprises methylmethacrylate or a copolymer of methacrylic acid and methyl methacrylate.

7. A drug delivery composition according to claim 2 wherein the coating comprises a cellulose ester.

8. (Amended) A drug delivery composition according to claim 1 wherein the coating has a thickness in the range of 80 μm to 300 μm .

9. (Amended) A drug delivery according to claim 1 wherein the drug is one which acts locally in the colon.

10. (Amended) A drug delivery composition according to claim 1 wherein the drug is for systemic delivery and systemic action.

AMENDMENT AND RESPONSE TO OFFICE ACTION

11. (Amended) A drug delivery composition according to claim 1 wherein the drug is a vaccine for delivery to the lymphoid tissue of the colon.

12. A method of delivering a drug to the colonic region of a human or mammal comprising orally administering a drug delivery composition comprising a starch capsule containing the drug and wherein the starch capsule is provided with a coating such that the drug is predominantly released from the capsule in the colon and/or terminal ileum.

B2 13. (Twice amended) A method of delivering a vaccine to the lymphoid tissue present in the colon of a human or mammal comprising orally administering a drug delivery composition comprising a starch capsule containing the vaccine and wherein the starch capsule is provided with a coating such that the vaccine is predominantly released from the capsule in the colon and/or terminal ileum.
